image maker

pspix

USER MANUAL

SOPRO

ACTEON Imaging

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1. FOREWORD

Congratulations on your purchase of PSPIX.
To optimize the use of this device, whilst taking all the necessary precautions, we recommended you carefully read and follow the present owner's manual.

Please carefully consider the messages "CAUTION", "WARNING", and "NOTE" when using the system.

⚠ CAUTION: the term CAUTION describes potential incidents likely to jeopardize safety.

! WARNING: the term WARNING refers to the incidents likely to disturb the smooth running of the imaging system.

NOTE: the term NOTE highlights particular points in order to facilitate the system maintenance or to clarify important information.

2. PSPIX INTRODUCTION

2.1 FUNCTIONS AND PERFORMANCE

PSPIX is a laser-scanning device designed to automatically scan, read and erase reusable dental intraoral imaging plates.

PSPIX works in conjunction with a PC installed with compatible dental imaging software. The scanner can either be connected directly to the PC or to the network, via a LAN cable.

PSPIX can be set up to work with a single PC, the **single user** configuration, or with multiple PCs, the **multiconnect** (multiple users) configuration. The multiple user configuration allows up to eight PCs to control the scanner (there is no software limitations in consulting the image), one PC at a time.

2.2 PARTS LIST

The PSPIX digital intraoral imaging plate system is composed of the following elements:

- PSPIX scanner
- 2 standard imaging plates size 0
- 2 standard imaging plates size 1
- 5 standard imaging plates size 2
- 1 standard imaging plates size 3
- 100 protective covers for each standard imaging plate (except size 2 : 200 protective covers)
- 100 hygiene bags for each standard imaging plate (except size 2 : 200 protective covers)
- A microfiber cloth for cleaning imaging plates
- An imaging plate storage box,
- An imaging plate collector,
- A power supply 100-240 VAC.

In option:

- IDOT imaging plates, size 0, size1, size 2, size 3 for individually market plates.
- Imaging plate holders for bitewing, periapical and endodontic exposures.

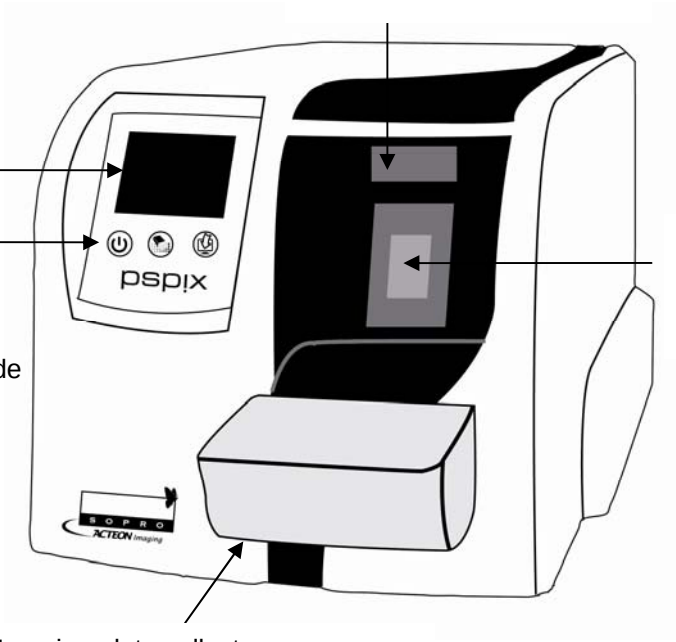
NOTE:

The device has been designed and developed with its accessories in order to guarantee maximum safety and performance. The use of non-genuine accessories may present a risk to you, your patients and/or your device.

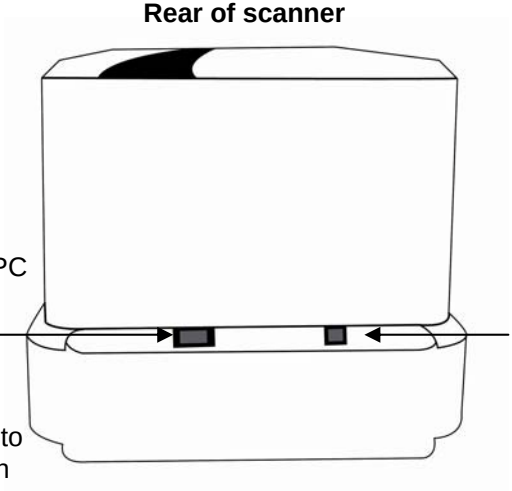
WARNING

USA only:
Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.

2.3 Main parts



Rear of scanner



3. PRECAUTIONS FOR USE

THE SCANNER IS A CLASS 1 LASER PRODUCT

• When covers are removed the scanner is a class 3B laser product – avoid exposure to the laser beam.

• Use of controls, adjustments or maintenance other than those specified herein may result in exposure to hazardous laser radiation.

• When handling imaging plates, plate covers and protective bags, always take the appropriate hygiene measures and precautions in order to prevent cross contamination risks.

• The imaging plates are harmful if swallowed.

• Do not move nor knock the PSPIX while it is performing its scanning process.

• This scanner can only be used to read image plates supplied by SOPRO. NEVER use imaging plates or protective covers from other manufacturers.

• This unit and its accessories must not be modified, altered or remanufactured in any way.

• Only the manufacturer's approved service personnel are authorized to conduct maintenance and/or repair procedures. There are no user serviceable parts inside the unit.

• Infection control procedures must be observed when using accessories such as film holders, x-ray tube guides and imaging plates. When using accessories always follow the manufacturer's instructions on how to use said accessory and prevent cross contamination risk from one patient to another.

• This device can interfere with other devices due to its EMC characteristics.

• Other devices can interfere with this device due to their EMC characteristics.

• This device complies with IEC 60601-1 standard. Accessory equipment connected to this device must be in compliance with the local IEC standards.

• This equipment is not suitable for use in the presence of flammable anaesthetic, mixture with air, oxygen or nitrous oxide.

• In order to maintain safe and correct function of the unit, only the power supply (PSU) supplied with the scanner or distributed from authorized dealer can be used. Please refer to the scanner's technical specifications for a list of compatible PSUs.

• Only use Imaging plates, protective covers and hygiene bags designed for this scanner and supplied by an authorized distributor.

3.2. SYSTEM OPERATING ENVIRONMENT

Refer to chapter 11 « Technical features ».

3.3. TRANSPORT AND/OR STORAGE ENVIRONMENT OF THE SYSTEM

Refer to chapter 11 « Technical features ».

3.4. PRECAUTIONS RELATED TO THE ETHERNET CONNECTIONS

For Ethernet connections, use a CAT6 LAN cable while avoiding multiple switches or hubs to be connected in cascade. The PC or Ethernet switch/hub into which the scanner is connected should be standards compliant (e.g. EN 60950, IEC 60950, UL 60950). After installation, check that the IEC 60601-1 current leakage levels are not exceeded.

4. STANDARDS AND REGULATIONS

4.1 Compliance with standards and regulations

This product was designed and manufactured by a company having an authorized quality system. It meets the European directive 93/42/EEC requirements relative to medical devices. Therefore, it particularly meets electrical safety and electromagnetic compatibility standards (IEC) (CEM).

4.2 Electromagnetic interference and electrostatic discharges

Electromagnetic compatibility (CEM) is the ability of electronic device elements to correctly interact in an electronic environment. Although PSPIX system was designed according to this compatibility and complies with the electromagnetic interference thresholds established by the regulatory agency, there is no guarantee about interference likely to occur on a particular installation.

If the device generates interference with radio communication services (which can be determined by switching it off and on), it is recommended to try to correct this phenomenon by taking whole or part of the following measures:

- Change the receiving antenna orientation
- Reposition the product according to the receiver.
- Take the computer away from the receiver.

PSPIX is designed and tested to be used in a home environment, class B Group 1, according to CISPR11 standard.

4.3 MEDICAL DEVICE VIGILANCE

As with any medical device, this device is subjected to medical device vigilance dispositions; any serious dysfunction should then be the subject of a description to the competent authorities and to the manufacturer as soon as possible and as precisely as possible.

4.4 END OF LIFE

This device bears the recycling symbol according to the European directive 2002/96/EC about electric and electronic equipment waste (DEEE or WEEE). By correctly disposing of this device, you will contribute to avoiding any damage to the environment and human health.

The symbol present on the device or on the accompanying documentation indicates this product cannot be, in any case, treated as household waste. Therefore, it should be transferred to a waste collection centre that handles

electric and electronic equipment recycling.
Please respect the standards relative to waste disposal in force in the installation country. For more details about the device treatment, recuperation and recycling, please contact your dental device distributor (or failing that, the group ACTEON site www.acteongroup.com), so that you can be informed of the procedure.

4.5 ELECTROMAGNETIC COMPATIBILITY

Guide and declaration of the manufacturer - electromagnetic emissions		
PSPIX device is intended to be used in the electromagnetic environment specified below. The user should make sure it is used in this environment.		
Emission trial	**Compliance**	**Electromagnetic environment - Guide**
RF emissions CISPR 11	Group 1	PSPIX device only uses radio energy for its internal functions. Therefore, its RF emissions are very low and are unlikely to cause interference with nearby electronic devices.
RF emissions CISPR 11	Class B	PSPIX device may be used in all domestic environments, including the ones directly connected to the public low voltage power distribution network used to supply household buildings.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations / Flicker EN 61000-3-3	Complies	

Guide and declaration of the manufacturer - electromagnetic immunity			
PSPIX device is intended to be used in the electromagnetic environment specified below. The user should make sure it is used in this environment.			
Immunity trial	**IEC 60601 Severity level**	**Compliance level**	**Electromagnetic environment Guide**
Electrostatic discharges EN 61000-4-2	± 6 kV when in contact ± 8 kV in the air	± 6 kV when in contact ± 8 kV in the air	The floor should be wooden, concrete or tile. If the floor is covered with a synthetic material, the relative humidity should be at least 30%.
Far transient bursts EN 61000-4-4	± 2 kV for the power supply lines ± 1 kV for the input/output lines	± 2 kV for the power supply lines ± 1 kV for the input/output lines	The main power supply quality should be one of a traditional commercial or hospital environment.
Voltage shocks EN 61000-4-5	± 1 kV Differential mode	± 1 kV Differential mode	The main power supply quality should be one of a traditional commercial or hospital environment.
Dips, brief outages and power voltage variation EN 61000-4-11	• <5% U_T – (>95% dip in U_T for 0.5 cycles) • 40% U_T (>60% dip in U_T for 5 cycles) • 70% U_T (>30% dip in U_T for 25 cycles) • <5% U_T (>95% dip in U_T for 5 cycles)	• <5% U_T – (>95% dip in U_T for 0.5 cycle) • 40% U_T (>60% dip in U_T for 5 cycles) • 70% U_T (>30% dip in U_T for 25 cycles) • <5% U_T (>95% dip in U_T for 5 cycles)	The main power supply quality should be one of a traditional commercial or hospital environment. If the user of PSPIX device requires it to continue to operate during main power supply outages, it is recommended PSPIX device is fed by an inverter or a battery.
Magnetic field with the network frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	The magnetic field with the network frequency should be at a characteristic level of a location in a traditional commercial or hospital environment.
Note: Ut is the power voltage nominal value applied during the trial.			

Guide and declaration of the manufacturer - electromagnetic immunity			
PSPIX device is intended to be used in the electromagnetic environment specified below. The user should make sure it is used in this environment.			
Immunity trial	**IEC 60601 Severity level**	**Compliance level**	**Electromagnetic environment Guide**
			Portable and mobile RF communication devices should not be used at a distance from PSPIX device including the cables, lower than the recommended separation distance, calculated with the applicable formulas depending on the emitter frequency. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vms 150 kHz to 80 MHz	3V	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum rated output of the transmitter in watts (W) by the transmitter manufacturer and d the recommended separation distance in metres (m). The field levels emitted by the fixed RF transmitters, determined by an electromagnetic measurement of the site **a**, should be lower than the compliance level in each frequency band **b**. Interference may occur in the vicinity of the devices bearing the following symbol:
Note 1: At 80 MHz and 800 MHz, the higher frequency band applies. Note 2: These recommendations may not apply in every situation. Electromagnetic wave propagation is modified by the absorption and reflection due to the structures, objects and persons.			

a The fixed transmitter field levels, such as the base stations of the radio telephones (cellular/wireless) and the terrestrial mobile radios, domestic radio, AM, FM, and TV radio communication cannot be theoretically assessed precisely. To obtain the electromagnetic environment due to the fixed RF transmitters, a site measurement should be performed. If a field level measured in the use environment of PSPIX device exceeds the compliance levels above applicable, the good operation of PSPIX device should be checked. If abnormal operations are proved, some further measures should be taken, such as reorientation or relocation of the standard device.

b Above the 150 kHz to 80 MHz frequency band, the field level should be lower than 3 V/m.

Recommended separation distances between the portable and mobile RF communication devices and PSPIX device

PSPIX device is intended to be used in an electromagnetic environment in which the irradiated RF disturbances are checked. The user of PSPIX device can help to avoid electromagnetic interference by maintaining a minimal distance between the portable and mobile RF communication devices (transmitters) and the recommended PSPIX device such as recommended below, depending on the maximum output power of the communication device.

Rated maximal output power of the transmitter W	**Separation distance depending on the transmitter frequency m**		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the transmitters whose maximum output is not listed above, the recommended separation distance **d** in metres (m) can be determined by using the equation applicable to the transmitter frequency, where *P* is the maximum output of the transmitter in watts (W) rated by the transmitter manufacturer.

Note 1: At 80 MHz and at 800 MHz, the separation distance given in the higher frequency band applies.

Note 2: These recommendations may not apply in every situation. The electromagnetic wave propagation is modified by absorption and reflection due to the structures, objects and persons.

4.2. SIGNIFICATION OF THE STANDARDISED SYMBOLS

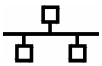
Indications symbols located on the label identifying the PSPIX digital intraoral imaging plate system are compliant with the international standards.

Dangerous voltage

Laser radiation

Caution, please consult the ACCOMPANYING DOCUMENTS.

Continuous voltage.



Ethernet connector RJ-45 straight cable

CE

0459

Product compliance according to the European directive 93/42/EEC relative to medical devices.

ETL symbol

Disposal of electric and electronic equipment marketed after 13/August/2005. This symbol indicates that the product cannot be treated with domestic waste.

5. SYSTEM CONFIGURATION

To use the PSPIX system, you must make sure the computer and its peripherals do not have any usage limitation that could endanger personal safety. The computer should also meet the following requirements:

	Minimal configuration	Recommended configuration
Operating system	Windows XP Pro SP2 or VISTA Business SP1	Windows XP Pro SP3 VISTA Business SP1
Processor	Intel® Pentium III – 500 MHz	Intel® Core 2
Memory	512 Mo	2 Go
Hard disk	80 Go	320 Go
Video board	Graphic board 128 MB of unshared video RAM compatible with DirectX 9	Graphic board with NVIDIA chipset or dedicated ATI video board / 512 MB of unshared video RAM, compatible with DirectX 9 or higher.
Ethernet board	100 Mb/s-1Gb/s	1 Gb/s
Screen resolution	1024 x 768	1024 x 768 or more
Standard	IEC 60950	IEC 60601-1

[!] WARNING

For Ethernet connections, use an unshielded CAT6 LAN cable, so that multiple chassis must not be connected! The PC/Ethernet switch to which scanner is connected to should be approved appropriately (e.g. EN 60950, IEC 60950, UL 60950).

5.2. IMAGING SOFTWARE

The PSPIX system is provided with Sopro Imaging, a dental imaging software compatible with Microsoft Windows (see table above for compatible versions). Sopro imaging software captures, processes, and stores x-rays acquired from the PSPIX system, images that can then be shared on the network.
Sopro Imaging can also link together with most popular management software available on the market. For more information, please contact your local distributor.

5.3. COMPATIBILITY WITH X-RAY GENERATORS

The PSPIX system is compatible with all intraoral x-ray generators. Nevertheless, we recommend X-Mind AC/DC generators that are perfectly adapted to the PSPIX system and insure very good performance and reliable x-ray images.

6. INSTALLATION AND CONNECTION

6.1. SOPRO IMAGING SOFTWARE INSTALLATION

• Insert the SOPRO Imaging CD-ROM into the driver. It will automatically start.

WARNING

If the CD-ROM does not execute automatically or if the operating system is prior to Windows XP SP1, follow these instructions:
- Go to the Start menu > Execute.
- Type D:\setup.exe (replace D with the letter of your CD drive).
- Click on OK: the installation process starts.

• A dialog box opens - it is the main menu window allowing the installation of a certain number of programs related to SOPRO Imaging.

NOTE

Clicking on the key "Browse this CD-ROM" opens an explorer window from which it is possible to browse the whole content of the CD-ROM.
At the CD-ROM root are files allowing an automatic launch and/or a manual setup.
- Located in the "Document" directory are all manuals related to Sopro Imaging software, digital x-ray systems, intra oral cameras and SOPROLIFE systems. These documents are in PDF format. Make sure Adobe Acrobat is correctly installed prior to opening any of those files.
- The drivers directories contain all the drivers necessary to pilot Sopro devices (PSPIX, Sopix system, SOPRO cameras in USB 1 and USB 2, Hasp protection key…).
- SOPRO Imaging directory contains the SOPRO Imaging installation program.
- The "Tools" directory contains Microsoft Direct X 9.0 c and ADOBE Acrobat Reader installation programs.

• Click on "Install SOPRO Imaging". A window appears; select the desired language to be used during the installation process.
• A dialog box opens - it displays the software license and terms of use to be entirely read in order to continue with the installation. Once read, click on "Next".
• By default, the SOPRO Imaging software will install in the "C:\Program Files\SOPRO Imaging" directory. It is possible in this dialogue to change the installation path. To start the installation click on "Next".
• Once the installation is completed, a dialogue box displays. Click on "Finish".

NOTE

To obtain the best possible performance when using the SOPRO Imaging software, it is recommended to install DirectX 9.0c. In order to do this, click on the button "Install DirectX 9.0c" and follow the displayed instructions. DirectX 9.0c is a Microsoft® product. In case of difficulties when installing this product, consult the information provided by Microsoft®.
In order to ensure maximal compatibility with all the installed systems (computers, Windows, and word processing version) it was decided to provide the documents available on the CD-ROM in PDF format.
This format developed by ADOBE® can be read using the Acrobat Reader service program.
If Acrobat Reader is not installed on the computer or the version is not recent enough, click on "Install Acrobat Reader" and follow the on-screen instructions. Acrobat Reader is an ADOBE® product. In case of difficulties when installing this product, consult the information provided by ADOBE®.

6.2 PSPIX SYSTEM INSTALLATION

- Before installing the PSPIX system, make sure the computer is connected to a correctly grounded outlet.

- Connect the PSPIX scanner to the computer using a Cat6 Ethernet cable, either directly to the computer, or via a hub/switch in case of a network setup.

WARNING

- *PSPIX shouldn't be exposed to direct sunlight nor should bright light or sunlight shine directly onto the scanner door into which the imaging plates are inserted.*
- *PSPIX should be located on a stable, flat surface in order to avoid vibrations that could in turn degrade the image quality.*
- *PSPIX can also be attached to a wall, under or on a shelf with the optional mounting kit.*
- *PSPIX can be positioned within the environment in which the patient is examined and treated (patient environment).*
- *PSPIX must not be stacked nor positioned in contact with other equipment.*

- Once PSPIX is connected to the PC or network, you need to install the drivers, located on the Sopro Imaging CD.

WARNING

Insert the Sopro Imaging software CD into the drive in order to install the drivers.

- Click on "Install PSPIX drivers".
- After a few moments, the installation is completed, click on « Finish ».

WARNING

The PC connected to the scanner should not be used in the patient environment.The minimum horizontal distance between the patient and the PC is 1.5 m. The minimum vertical distance between the patient and the PC is 2.5m.

6.3. SOPRO IMAGING SOFTWARE CONFIGURATION WITH A PSPIX SYSTEM

Refer to the Sopro Imaging owner's manual located on the Sopro Imaging CD in the "Document" directory in order to configure the system.

6.4. DISPLAY SYMBOLS ON PSPIX SYSTEM

Symbols and animations appear on the unit display during use :
These :

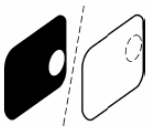
- Indicate the status of the scanner.
- Guide the user to operate the scanner correctly.
- Display a preview image.
- Show possible problems and guide the user to correct the problem.
- Guide user to check the application W on th workstation, if user action is required.
- Show any error codes

The basics symbols are shown below:

Startup

Unit door

Protective cover and imaging plate
White: remove protective cover



Imaging plate
White: wrong way round, rotate

Protective cover

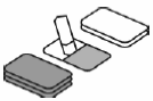
Remove / disconnect

Insert / connect

Multiconnect wait.
Multiconnect configuration, but the scanner has not been reserved. Waiting to be reserved form the PC.

Multiconnect reservation.
e.g: PC number 2 has reserved the scanner.

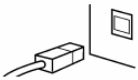
Busy. Scanner in operation.



Scanner in erasing mode

Check: something wrong or take alternative action

Dental imaging software not open, not ready or waiting for user action



Scanner not connected or connection not working

Rotate

Erase state and error number

Check documentation supplied with the scanner

Scanner in service mode (for service technical only)

7. USE

7.1. PREPARING THE PSPIX AND THE IMAGING PLATE

- Switch on the computer that is connected to the scanner.
- Open Sopro Imaging and then either create a new patient or open an existing one.

NOTE

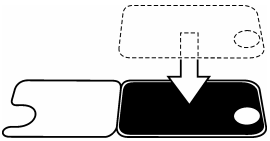
If you are using the system for the first time you may wish to check and/or change the setup options. Please refer to chapter 6.3.

- Turn PSPIX on by pressing the on/off button. A startup animation will appear on the display. The scanner will carry out self-tests and an initialization sequence during which time the plate carrier will slide out of the scanner door. When the status light turns green and the ready animation (showing the imaging plate insertion) appears on the unit's display, the scanner is ready for use.

NOTE

If the ready animation does not appear, check the system setup described in the in the chapter 6.3.

- The motion sensor allows hands free operations of the unit. When the scanner is in idle mode, the motion sensor detects the user's hand as it approaches the scanner and automatically wakes the scanner from idle to ready state.



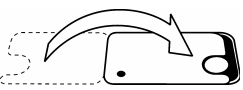
Place the imaging plate you wish to use onto the plate cover. The **active** side of the imaging plate (blue colour) must face the corresponding side of the protective cover.

WARNING

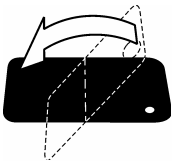
If the imaging plate is being used for the very first time or has not been used within the last 24 hours, it MUST initially be erased in order to avoid possible fogging caused by background radiation. Please refer to chapter 8.5.

CAUTION:

When handling imaging plates, protective covers and hygiene bags, take all appropriate measures and precautions in order to prevent cross contamination risks.

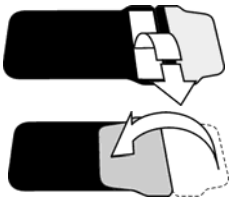


Fold the other half of the protective cover with the semicircular cut-out over the imaging plate. The metal disk on the back (black side) of the imaging plate will follow the shape of the semicircular cut-out.



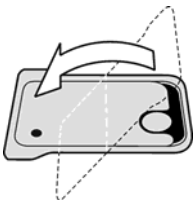
Turn the protective cover and imaging plate over so the black side of the protective cover is facing up. This makes it easier to slide it into the hygiene bag.

Slide the protective cover and imaging plate into the hygiene bag. The black side of the protective cover must correspond to the black side of the hygiene bag.



Peel off the cover paper from the sealing tape and fold the flap along the pre-formed line, over and onto the sealing tape.

Press and slide your finger and thumb along the tape to ensure that the flap is tightly sealed.



Turn the hygiene bag over and check that the imaging plate and protective cover are in the correct position. You should be able to see the white side of the protective cover as well as the metal disk located on the back of the imaging plate.

7.2. IMAGING PLATE HOLDERS

Correct positioning of the imaging plate as well as correct aiming of the X-ray beam are essential for image consistency and quality.

Manually positioning the Imaging Plate and not using a x-ray device aiming aid causes errors such as:
- Incorrect vertical angulations
- Distortion
- Cone cutting
- Poor standardization

Using a recommended holder system for holding the imaging plates guarantees optimally clear images:
-Exact positioning of the imaging plate relative to the tooth
- No IMAGING PLATE bending and thus no distortion
- No IMAGING PLATE movement
- Standardized, distortion free and reproducible images
- No overlapping
- No cone cut
- No excessive wearing or damage of the imaging plates
- No ocular guesswork
– Exclusive, automatic reliance on the extra-oral aiming and centring device

Using the recommended holder system improves the quality:
- Constant X-ray quality over time
– Whoever takes the X-Ray

Using the recommended holder system increases profitability:
- Easy to use system saves time
- Delegate work to hygienists

Contact your authorized distributor for more information on the holder systems.

7.3. ACQUISITION OF AN X-RAY IMAGE

- Place the sealed protective bag in the patient's mouth, in the required position for the image you wish to take. The back of the hygiene bag, black side, must face the X-ray source.
- Select an exposure value appropriate for the image you are taking. The scanner tolerates a relatively wide range of exposure values, so in practice it should be possible to use the same settings for all imaging purposes. However, it is recommended that ALARA (as low as reasonably achievable) principle is observed. Use the minimum

radiation dose to obtain images of sufficient quality that can be used for correct diagnostic purposes.

-

NOTE

If the exposure times are too long:
- the images may become too dark
- the images may be blurred because of patient movement.
- patient is exposed to too much X-ray radiation.
If the exposure times are too short:
- images may become too noisy and thus unclear.
-images may be different sizes than the actual objects.

- **Protect yourself from radiation** and take the exposure.

- After the exposure, remove the sealed hygiene bag and imaging plate from the patient's mouth.

⚠ CAUTION:

If there is a risk of cross contamination, wash, disinfect and dry the hygiene bag prior to opening it.

7.4. READING THE IMAGING PLATE

Single user configuration

- Make sure that the scanner is ready for IMAGING PLATE readout. The status light is green.

⚠ CAUTION:

If the status light is orange, the scanner is in standby mode. Press the **Start** key to exit the standby mode.

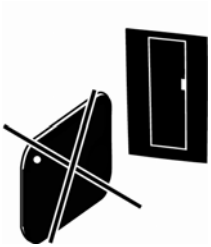
NOTE

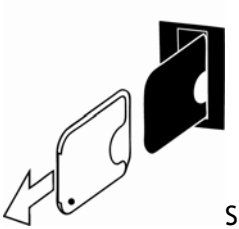
If the scanner is operated in a multiconnect configuration, please refer to the end of this section for multiconnect operations.

Pull the flap to open the hygiene bag.

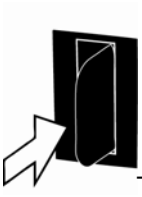
Slide the protective cover and imaging plate out of the hygiene bag. Keep the imaging plate in the plate cover so that you do not touch the imaging plate or allow it to be exposed to ambient light.

Hold the protective cover and imaging plate so that the white side of the protective cover (NOT THE BLACK) faces right. (The black side, back of the imaging plate, will also be on the right).


Insert the protective cover and imaging plate into the scanner door. A magnet will hold the imaging plate in the correct position.



Slide the plate cover off the imaging plate, and leave the imaging plate in position half way in the unit door.



The scanner has a proximity sensor, it detects when the imaging plate is near the unit door.

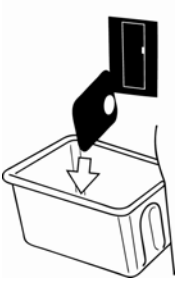
- After the protective cover has been removed the imaging plate will automatically slide into the unit.
- An animation will appear on the display, which indicates the imaging plate is being read.
- After a few seconds a preview image will appear on the scanner display.
- A read-out progress window will appear on the PC display. After a few seconds the new image will appear in the dental imaging software.
- Save the image in accordance with the information given in the dental imaging software you are using.

⚠ CAUTION:

There is a metal disk on the rear of every imaging plate. If the metal disk on the imaging plate can be seen on the digital image, it indicates that the imaging plate was exposed from the wrong side.

⚠ CAUTION:

If an image is not transferred to the PC because of a network, PC or software failure, the last image taken can be retrieved from the unit's memory
For information on how to do this see section Retrieve last image.



After the imaging plate has been read it will automatically be erased and ejected from the scanner into the plate collector. After the imaging plate has been ejected the ready symbol will reappear on the display. The scanner is now ready to read the next imaging plate.

⚠ CAUTION:

If the imaging plate does not slide into the unit after the protective cover has been removed, the imaging plate is misaligned or has been placed in the unit the wrong way round. Re-insert the imaging plate correctly.

Multiconnect configuration

- To reserve the scanner click the **GREEN** multiconnect icon, which is in the System Tray in the bottom right-hand corner of the PC display. The **Connect** window will appear.
- In the **Connect** window click the **"Reserve the Scanner"** button in order to reserve scanner.
- A window will disappear and the **GREEN** multiconnect icon will start to flash. This indicates that you have now reserved the scanner.

NOTE

If others users in the multiconnect configuration try to reserve the scanner the following message will display on their PC :
"Scanner reserved by XXXX (XXX is your multiconnect ID)" .

NOTE

If the multiconnect icon is YELLOW, it indicates that someone else has already reserved the scanner. Wait until the scanner is free.

NOTE

If the multiconnect icon is GRAY, it indicates that the scanner has not been switched on or is just starting up and is not yet ready for use. Switch the scanner on and/or wait until the scanner is ready for use.

- To release the scanner click the **GREEN** multiconnect icon.
- Then click the **Free the scanner** button.

Standby mode

- If no imaging plate is inserted into the scanner within a certain period of time, the unit will beep five times and the status light will start to flash. When it turns orange the unit is in the standby mode.
- The unit will automatically exit the standby mode as soon as a new imaging plate is presented in front of the unit.
- Press the **Start** key to exit the standby mode.
- After four hours the unit will exit the standby mode and automatically shut down.

7.5. REMOVING IMAGING PLATES FROM THE PLATE COLLECTOR

- When picking up imaging plates, hold them by there edged only.
- Alternatively, pull the plate collector out of the scanner and tip the imaging plates out onto a flat surface. If they are not to be used again immediately or within a short period of time, store them in the dedicated storage box. When picking up imaging plates lift them by their edges only.

7.6. RETRIEVE LAST IMAGE

Because of a network, PC, software or other communication failure, the last image scanned can be retrieved.

NOTE

The LAST read image can only be retrieved if the scanner is left on. If the scanner is switched off the image will be lost.

To retrieve the last image:

- Correct the problem that caused the communication failure and the connection will be re-established and the last read image should automatically be transferred to the PC.
- If it is not, select **File menu>Setup>PSPIX tab** from Sopro Imaging software.
- In the **Retrieve Last Image** field, click the check box to retrieve the last read image.

NOTE

If required you can select different parameters (e.g. resolution setting, show image preview etc.) for the image to be retrieved.

- Click **OK** to close the **Setup** window. The last read image will appear on the patient card.

7.7. SHUTTING DOWN THE SCANNER

- Press and hold power on / off key until the indicator light goes off.

NOTE

If there is an untransferred image in the unit's memory the unit cannot be shut down. Refer to the chapter **Retrieve last image**.

8. IMAGING PLATE

8.1. GENERAL INFORMATION

An Imaging Plate is a flexible intraoral x-ray image receptor comprising a layer of very small particles of photo-stimulable phosphor uniformly coated onto a polyester support film and shielded with a top coat protective layer.

Phosphor / phosphorous:
Phosphorous / phosphorus (P) is not used in our plates.
In our application, we consider phosphor as a substance that exhibits the phenomenon of phosphorescence (sustained glowing after exposure to stimulating laser beam during readout)

Phosphor material sealing:
Phosphor material is properly sealed inside the top coat protective layer on the active side and the support material on the back side. The edges are sealed with a edge reinforcement layer. Phosphor substances cannot become detached from the other IMAGING PLATE components in normal use.

With imaging plates the phosphor particles are excited by X-ray photons and store the X-ray energy in the form of a latent image.

The latent image held by the phosphor particles is stable for hours and takes several days to finally decay. When the imaging plate is read by the imaging plate scanner, the latent image is stimulated by a laser, activated and then converted to digital form. The digital image can then be view on the PC.

After the latent image has been read and converted to digital form the image is automatically erased so that the IMAGING PLATE is ready for immediate re-use.

• The light blue side of the imaging plate is the side which “stores” the X-ray image. It is the SENSITIVE side!
• X-ray exposures DO NOT cause imaging plates to age. Imaging plates can withstand thousands of exposures without degradation of performance.
• After an imaging plates has been exposed it is sensitive to ambient light and should be protected from direct light and daylight by keeping it in its protective cover until the plate is read.
• Read exposed images immediately after exposure to avoid image information loss.
• Proper handling is the main factor that extends the service life of imaging plates.

8.2. HANDLING IMAGING PLATES

The correct use, handling, cleaning and storage of imaging plates guarantees the best image quality and maximum service life of the imaging plates.

X-ray exposures DO NOT cause IMAGING PLATEs to age. The light (blue) side of the imaging plate is the side which “stores” the x-ray image. It is the SENSITIVE side!

• Only hold imaging plates by their edges using your fingertimaging plates.
• Unprotected IMAGING PLATEs should not come in contact with the patient, the patient’s saliva or any other bodily fluids.

Protect the SENSITIVE side of the IMAGING PLATE from:
• Scratches, wear and other mechanical abrasion or damage
• Stains, dirt, dust particles etc.
• Fingerprints

Stains / fingerprints on the sensitive side can degrade the diagnostic value of the image. Dust / wear on the sensitive side can appear as white/grey spots on the image!

Image information “stored” on an imaging plate after an exposure is sensitive to light.

Always use hygiene bags and protective covers with imaging plates when taking exposures to:
• eliminate cross contamination
• maintain image quality
• maximize IMAGING PLATE service life.

Précautions for use :
• Handle Imaging plate with the same care as you would handle intraoral film, CD or DVD disks.
• Only hold IMAGING PLATEs from the edges.
• Never use tweezers, pliers or any mechanical devices to pick up / handle IMAGING PLATEs.
• Do not touch the sensitive surface of the IMAGING PLATE with fingers or nails.
• Do not get fingerprints, stains, dirt or dust on the sensitive side of the IMAGING PLATE.
• Protect the sensitive side of the IMAGING PLATE from, scratches, wear and other mechanical abrasion or damage.
• Avoid excessive bending of the plate
• Avoid applying pressure to the IMAGING PLATE with anything that could mark or leave an imprint on the sensitive side.

• Unprotected IMAGING PLATEs should not come in contact with the patient, the patient's saliva or any other bodily fluids.
• Always use protective covers and hygiene bags with IMAGING PLATEs when taking exposures to eliminate cross contamination, maintain image quality and maximize IMAGING PLATE service life.
• Any scratches, stains, dirt, fingerprints or dust on the sensitive side of the IMAGING PLATE can affect image quality and can interfere with diagnostic value of the image.
Dust and wear on the IMAGING PLATE will appear on the image as white or grey dots.

8.3. REPLACING IMAGING PLATES

An IMAGING PLATE should be replaced if:

• there is sign of active side damage/wearing visible on the image so that it may interfere with a diagnosis
• there are clearly visible scratches
• there are clearly visible spots or dots, which do not disappear by proper cleaning
• the active surface is worn or damaged in any other way
• the above mentioned artefacts do not disappear with proper cleaning
• the protective layer of active surface is damaged
• the plate is torn or badly bent

8.4.GENERAL STORING AND INITIAL ERASING GUIDELINES

• IMAGING PLATEs are sensitive to background radiation. If an IMAGING PLATE that has been exposed to background radiation is used to take a patient exposure the image quality may be degraded, for example reduced contrast.
• When not in use IMAGING PLATEs should be stored in the supplied storage box in bright ambient light. Light will erase image fogging, caused by background radiation, from the IMAGING PLATEs. Initial erasing of IMAGING PLATEs before patient exposure is unnecessary if the IMAGING PLATEs are properly stored as described above. Storing IMAGING PLATEs in the storage box will also protect them from dust.
• To avoid scratching IMAGING PLATEs never leave unpacked IMAGING PLATEs lying on a surface, especially with active side facing down.
• Do not store IMAGING PLATEs in hot or humid conditions (store below 33°C / 80% RH).
• Do not expose IMAGING PLATEs to X-ray radiation.
• Do not expose IMAGING PLATEs to ultraviolet radiation.
• IMAGING PLATEs can be stored in their protective covers and hygiene bags for briefs period of time if protected from background radiation. However if they

are stored in such conditions for more that 24 hours it may be necessary to initially erase the IMAGING PLATEs before using them for patient exposures.

This can be done by :
- reading the IMAGING PLATE normally with unit before using the IMAGING PLATE for patient exposure (from the image you can see whether there is fogging on the IMAGING PLATE).
OR
- Select the dedicated erasing mode.

Whether the initial erasing is required depends on the ambient conditions in which the IMAGING PLATEs are stored.

8.5 IMAGING PLATE ERASING MODE (INITIAL ERASING OF THE IMAGING PLATES)

If an imaging plate is being used for the very first time or has not been used for the last 24 hours, the erasing procedure must be carried out in order to remove any fogging due to background radiation.

The dedicated erasing mode erases Imaging Plates quickly and efficiently and does not send a blank image to Sopro Imaging software.

- Press and hold down the **Start** key for several seconds until the erase mode animation appears on the unit display. The unit is now in the erase mode.
- Hold the IMAGING PLATE by its sides (or use a protective cover) and position it so that the back of the imaging plate (the BLACK side) is on the right. Insert the IMAGING PLATE into the unit door (remove the protective cover if used). A magnet will hold the imaging plate in position and then automatically slide the IMAGING PLATE into the unit.

NOTE

It may take longer to erase IMAGING PLATEs using the erasing mode than the normal readout and erase mode. This is to ensure that IMAGING PLATEs that have not been used recently are erased properly.

- After the imaging plate has been erased it will automatically be ejected from the scanner into the plate collector. The imaging plate can now be used to take an exposure.
- To exit the Erasing mode, either wait 15 seconds for the scanner to automatically exit the mode, or press and hold down the Start key until the erase animation disappears.

9. MAINTENANCE

The PSPIX system does not need any maintenance if it is used according to the manufacturer's use and cleaning instructions.

Before first using any device from the PSPIX, it is imperative to follow the complete disinfecting procedure.

Any device from the PSPIX returned to the manufacturer or distributor for servicing or maintenance should be carefully disinfected before shipping.

Any item of the PSPIX range coming back from servicing or maintenance operation should follow complete disinfecting procedures before being used.

Proper use, handling, cleaning & storing guarantees the best image quality and maximizes the lifetime of your imaging plates!

Controller maintenance

DESCRIMAGING PLATETION	RECOMMENDATIONS	USE INSTRUCTIONS AND PRECAUTIONS		WARNING
		✓	⊗	
Cleaning the unit	Use a non abrasive cloth moistened with either: - cool or lukewarm water, - soapy water, - mild detergent, - butylalcohol, - ethanol (ethyl alcohol) 70 - 96%.	After cleaning wipe the scanner with a non abrasive cloth moistened with plain water.	•Never use solvents or abrasive cleaners to clean the unit. •Never use unfamiliar or untested cleaning agents.If you use a spray cleaning agent •DO NOT spray it directly at the open or closed scanner door	• Switch off and disconnect the scanner before cleaning or disinfecting it. • Do not allow any liquid to enter the unit.
Disinfecting the unit	Wipe the scanner with a cloth dampened with a suitable disinfectant solution such as ethanol 96%	• All surfaces must be dried before the scanner is used.	• Never use abrasive, corrosive or solvent disinfectants.	• Wear gloves and other protective clothing when disinfecting the unit. • Do not use any disinfecting sprays as the vapor could ignite causing injury.

NOTE

Disinfecting techniques for both the scanner and the room where the scanner is used must comply with all local and national regulations and laws concerning such equipment and its location.

Imaging plate maintenance

DESCRIMAGING PLATETION	RECOMMENDATIONS	USE INSTRUCTIONS AND PRECAUTIONS		WARNING
		✓	⊗	
Clean the sensitive side of the IMAGING PLATE if there are any visible artefacts (which are not obvious scratches) on the image	• Use a soft, lint-free tissue (for example microfibre tissues for optics are excellent) • First wipe in a back and forth direction and then with circular movement • If there's still stains after wiping with dry tissue, dampen one corner of the tissue with 70…96% ethanol (also called ethyl alcohol) and wipe as described above. • Wipe the active surface dry with the dry part of your tissue.	SUITABLE CLEANING SOLUTIONS FOR IMAGING PLATES: • 70 to 96 % ethanol (70…96 EtOH / 30…4 DI WATER) • Ethanol anhydride (= Anhydrous alcohol) • Single use "foil packed" or "dispenser packed" etc cleaning tissues containing	DO NOT USE FOR CLEANING: • Phenol based cleaning liquids • Isopropyl (= 2-propanol, Isopropanol, Isopropylic alcohol) • Acetone etc. solvents • Autoclave • Disinfectant baths. • Abrasive cleaning agents	• Unsuitable cleaning solution may leave residue on the active surface which will appear as artefacts on the images • Unsuitable cleaning solutions/methods may damage or destroy the imaging plate

• Clean the sensitive side of the IMAGING PLATE if there are any visible marks or artifacts (which are not obvious scratches) on the image
• Use a dry lint-free cloth (a microfibre cloth used for cleaning lenses, or similar)
• First very gently wipe the IMAGING PLATE in a backwards forwards in both the vertical and horizontal direction and then finish with a circular wiping movement.

NOTE

Avoid excessive wiping of the manufacturing batch- and IDOT –markings with alcohol. Markings will withstand cleaning, but may start to fade with repeated and excessive rubbing and wiping, especially if alcohol is used for cleaning.

10. AFTER SALES SERVICE

10.1 LIMITED LIABILITY

The PSPIX system is designed to ensure the acquisition of dental x-ray images, their transfer in the form of computer data as well as their storage. Nevertheless, SOPRO cannot be liable for inappropriate use of this material or for any loss of data.

10.2 WARRANTIES

SOPRO insures the absence of material and manufacturing defects for its products during a period of one (1) year coming into effect at the purchase date. This warranty does not apply to misused, modified, untended, or accidentally damaged products, or products subjected to abnormal use and handling conditions. The distributors, other than ACTEON Group's subsidiaries, are not authorized to apply a warranty further extended on behalf of SOPRO.

The entire liability of SOPRO is limited to its convenience either when replacing or repairing (free of charge) the defective product if it has been sent to SOPRO After-Sales Service. This applies for the entirety of the warranty period.

Outside France, access to the warranty is only possible if the product was bought in one of the Sopro authorized points in the country where it will be used.
THIS WARRANTY CONSTITUTES THE ONLY AND UNIQUE REMEDY. IT REPLACES ANY OTHER WARRANTY (FOR EXAMPLE, WARRANTY OF ADEQUACY TO A PARTICULAR AIM) WHETHER IT BE EXPLICIT OR IMPLICIT. SOPRO SHALL NOT BE LIABLE FOR ANY PARTICULAR DAMAGE (INDIRECT, ACCIDENTAL OR CONSEQUENTIAL) OR FOR ANY DETERIORATION OR DATA LOSS ON A CONTRACTUAL, NON-CONTRACTUAL OR OTHER BASIS.

The liability exclusion or limitation for direct or indirect damages does not apply under the regulatory or legal rules in force in some countries and the present exclusion may not apply to a purchaser in those countries.

10.2 IN CASE OF FAILURE

Problems	Causes	Solutions
The unit won't wake up from sleep	The motion sensor might have failed	Press the 3rd button on the unit in order to wake the unit up
The tray won't come out	A protective cover or imaging plate fell inside the unit	Please contact our after sales service.
The screen instructs to plug in the Ethernet cable.	The cable is not connected to the network, or the cable is faulty.	Check the hub or switch the unit is connected to is turned on, and that the cable is fully inserted in the plug. If nothing works, change the cable.
The screen shows a blinking application window.	There is a communication error between the unit and software	Start/restart the software and check the configuration of both the unit and the software (refer to Sopro Imaging's user manual).
The following message may appear on the PC screen during or after read-out : "Degraded image quality"		If the image looks okay no action is necessary. If the message appears frequently, contact your authorized distributor for assistance.

In case of failure not mentioned above, please send the PSPIX system back to the SOPRO dealer or after-sales department.

⚠ CAUTION:

No maintenance should be performed by a third party.

11. TECHNICAL SPECIFICATIONS

PSPIX

Dimensions (H x W x D): 203 mm x 246 mm x 411 mm
Weight : 9.5 kg
Operating voltage: 24 VDC (PSU: 100 – 240VAC, 50/60Hz)
Operating current: less than 1.5 A
Pixel size, selectable: 35 µm (super) 64 µm (high)
Bit depth: 14 bits grayscale
Clinical Resolution: 10 lp/mm
Spatial Resolution: 14.3 lp/mm

- Operating environment: +10°C to +40° C, 30 to 90 RH%, 700 to 1060 mbar.
- Storage/transportation environment: -10°C to +50° C, 0 to 90 RH%, 500 to 1080 mbar.
- Interface cable: For Ethernet connections, use an unshielded CAT6 LAN cable, so that multiple chassis must not be connected! The PC/Ethernet switch to which scanner is connected to should be approved appropriately (e.g. EN 60950, IEC 60950, UL 60950).
- Continuous service.
- Not protected against water chutes (IPXO)
- Class 1 or 2 equipment depending on the classification of the PSU. No applied part.
- Power supply: POWERBOX EMX 805121
- Class 1 laser product EN 60825-1 :2007
- Complies with IEC 60601-1.

IMAGING PLATES

Imaging plate Size 0
Dimensions: 22 x 31 mm
Image size (pixels)35 µm: 628 x 885 pixels
Image size, 35 µm: 1085 KB
Image size (pixels)64 µm: 484 x 344 pixels
Image size, 64 µm: 325 KB

Imaging plate Size 1
Dimensions: 24 x 40 mm
Image size (pixels) 35 µm: 685 x 1143 pixels
Image size, 35 µm: 1529 KB
Image size (pixels)64 µm: 625 x 375 pixels
Image size, 64 µm: 458 KB

Imaging plate Size 2
Dimensions: 31 x 41 mm
Image size (pixels) 35 µm: 886 x 1171 pixels
Image size, 35 µm: 2026 KB
Image size (pixels)64 µm: 641 x 484 pixels
Image size, 64 µm: 606 KB

Imaging plate Size 3
Dimensions: 27 x 54 mm
Image size (pixels), 35 µm: 771 x 1542 pixels
Image size, 35 µm: 2322 -KB
Image size (pixels)64 µm: 844 x 422 pixels
Image size, 64 µm: 695 KB

STORAGE:
• Unpacked, exposed to ambient light in the dedicated storage box. The box must be kept closed to remain dust free.
• Below 33°C / 80% RH and shielded from X-ray or ultraviolet radiation.

MATERIAL:
• photo-stimulable phosphor uniformly coated on a support plastic material. Shielded with a top coat layer on active surface and encapsulated with lacquer around edges.

DISPOSAL:
• Imaging plates are industrial waste and must be disposed of in accordance with local and national regulations concerning the disposal of such material.

HYGIENE BAGS

MATERIAL:
• Food-grade polyethylene – Latex free.

PACKAGING:
• Supplied in boxes

DISPOSAL:
• Observe relevant national requirements.

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SOPRO
ACTEON Imaging

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